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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/502,176	02/10/2000	Steven Piric-Shepherd	05940-0141	4843

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EXAMINER

HARRIS, ALANA M

ART UNIT PAPER NUMBER

1643

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/502,176

Applicant(s)

PIRIE-SHEPHERD ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-9,15,16,27,29,35 and 37-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35 and 37-40 is/are allowed.
- 6) ☒ Claim(s) 1-4,6-9,15,16,27,29 and 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments and Arguments

1. Claims 1-4, 6-9, 15, 16, 27, 29, 35 and 37-43 are pending.
Claims 39-43 have been added.
Claims 1, 4, 29, 35, 37 and 38 have been amended.
Claims 10-12, 30-34 and 36 have been cancelled.
Claims 1-4, 6-9, 15, 16, 27, 29, 35 and 37-43 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejection

Claim Rejections - 35 USC § 103

3. The rejection of claims 1-4, 6, 8-9, 11, 15, 16, 29, 35, 37 and 38 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,837,682 (issued November 17, 1998) has been withdrawn in light of Applicants' amendments to the claims, as well as their arguments. Claims 10, 30-33 and 36 have been cancelled.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. The recitation "[T]he composition" in claims 41-43 lacks antecedent bases in claim 27.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

Art Unit: 1643

directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-4, 6-9, 15, 16, 27 and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2003/0012792 A1 (effective filing date May 22, 1998). This rejection was previously presented in the Action mailed February 11, 2005 and improperly withdrawn in the Action mailed August 22, 2005. The Examiner has reviewed all of the parent applications and the provisional application from which priority depends and the amino acid sequence consisting of 260 amino acids is listed as Sequence number 1 in all of these documents.

U.S. patent application publication #2003/0012792 discloses a human sequence 61, a peptide of 260 amino acid residues which is the same as Applicants' SEQ ID NO: 2 deglycosylated kringle 1-3 region fragment within a composition comprising a pharmaceutically acceptable carrier, see attached sequence alignment and pages 70 and 71 of patent application and section 0081 provided with the Action mailed February 11, 2005. The disclosed angiostatin elicits antiangiogenic activity *in vitro* and *in vivo*, see page 5, section 0078.

8. Claims 1-4, 6, 8, 9, 15, 16 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 5,837,682 (issued November 17, 1998). U.S. Patent discloses a kringles 1-3, a fragment beginning at approximately amino acid 87 of human plasminogen, which can be combined with pharmaceutically acceptable excipients, see

Art Unit: 1643

column 9, lines 9-13 and 45-49; column 21, lines 5-28; column 22, lines 25-59; column 23, lines 7-21; and column 58, lines 45-53. It is art known that *E. coli* produced proteins are free of glycosylation. Kringles 1-3 is an angiostatin fragment meaning a protein derivative of angiostatin used to inhibit or suppress tumor growth, see Example 19 within columns 35 and 36; column 41, lines 19-23; and column 42, lines 47-65; Figure 13 and corresponding legend in column 7, lines 46-48; Figures 15A-C, 16A-C; and their corresponding legends in column 7, lines 54-60; column 42, lines 47-55.

Allowable Subject Matter

9. Claims 35 and 37-40 are allowed.

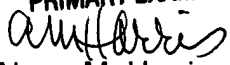
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER


Alana M. Harris, Ph.D.
01 February 2006